JUN 13 2011

510(k) Summary (21 CFR 807.92)

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

"The assigned 510(k) number is K110374" (applicant leave blank)

Premarket Notification [510(k)] Summary

[1]]. The summary contains the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared:

Submitter's Name: Medicore Co., Ltd.

Submitter's Address: 1F, Delice B/D B, 135-5, Sangdeawon-dong, Jungwon-gu, Sungnam-si, Gyunggi-do, Korea

Phone Number: 82-2-2056-2650

Fax Number: 82-2-2056-2688

Name of Contact Person: Mr. Byung-kuk Yoo

Date the Summary was prepared: November 8, 2010

[2]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if know.

Product Name: Max Pulse System

Common Name: Pneumatic Plethysmograph

Classification: JOM; Class II;

Regulation Number: CFR 21 870.2780

[3]. An identification of the legally marketed device to which your firm is claiming substantial equivalence.

Predicate Device: McPulse by Meridian Co. Ltd.

[4] A description of the device

Description of Device: The device is to measure the heart rate with photoelectric measurement techniques. It is to be connected with a desktop PC or laptop PC. It is operated with a mouse or a keyboard of PC which is used to enter the patient information as well as to operate the system and review the resulting analysis.

	Predicate Device	**Subject Device**
	McPulse Meridian Co. Ltd K023238	Max Pulse Medicore, Co., Ltd.
Classification	Class II	Class II
Classification Code	JOM	JOM
Intended Use	Measures pulse waveform; SpO2 and heart rate by photoelectric plethysmograph	Measures pulse waveform; SpO2 and heart rate by photoelectric plethysmograph
Intended Users	Professional use only	Professional use only
Mode	Non invasive	Non invasive
Display	Digital LCD display	No
Power Source	AC (100-240Vac, 50/60 Hz)	100~240VAC Phase: Single Frequency 50/60Hz Current less than 1.0A

Type of Sensor	LED – photodiode/finger probe	LED – photodiode/finger probe MD-10 finger type reusable sensor Accuracy±2% Shape Clip type Led specification Red & infrared, nominal Photodiode Active area : 5mm^2 Responsibility : 0.18Min
Recorder Outputs	Pulse waveform Heart rate	Pulse waveform Heart rate
Heart Rate Range	30-230 bpm	30-240 bpm
Size (unit:mm)	305.5 W x 296 H x 92.5 D	150x 130x 35
Weight	Approx 5.5 kg	Approx. 650g
Safety features	Compliant with applicable safety standards	Compliant with applicable safety standards
Environmental Conditions Operation	Not specified in product labeling	Temperature 10-35°C Relative humidity 20-95%RH Atmospheric Pressure 700-1060hPa
Environmental Conditions Storage	Not specified in product labeling	-20~60°C(-4~140°F) 10~90% RH @ -25~65°C(-13~149°F) 700~1060hPa

[5]. The summary describes the intended use of the device.

Intended Use: The device provides noninvasive measurement of heart rate by photoelectric probe. The anatomical site for taking the measurement is the left index finger. The device is intended for use with patients age 18 years and older and with a weight of 100 lbs or greater. The device is indicated for use in hospitals, health care clinics and physicians' offices

[6] A brief discussion of the nonclinical submitted, reference, or relied on in the premaket notification submission for a determination of substantial equivalence.

Clinical data is not needed for Max Pulse system or for most devices cleared by the 510(k) process.

[7] Performance:

The device has completed performance testing showing that the functions are substantially equivalent to the predicate. In addition the device meets the same safety and performance standards as the predicate.

[8]The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

The Medicore Max Pulse System is substantially equivalent[1] to the McPulse device manufactured by Meridian Co. Ltd. that received clearance through 510(k) Premarket Notification K023238 and currently in commercial distribution.

[1] The term "substantially equivalent" as used in this submission is intended to convey only a determination of substantial equivalence pursuant to the requirements of the FD&C Act. It is not intended to have any bearing whatsoever in determining what is patentable or on the resolution o patent infringement suits or any other patent matter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medicore Co., Ltd.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

JUN 13 2011

Re: K110374
Trade/Device Name: Max Pulse
Regulation Number: 21 CFR 870.2780
Regulation Name: Photoelectric, Pneumatic, or Hydraulic Plethysmograph
Regulatory Class: Class II (two)
Product Codes: JOM
Dated: May 27, 2011
Received: May 31, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

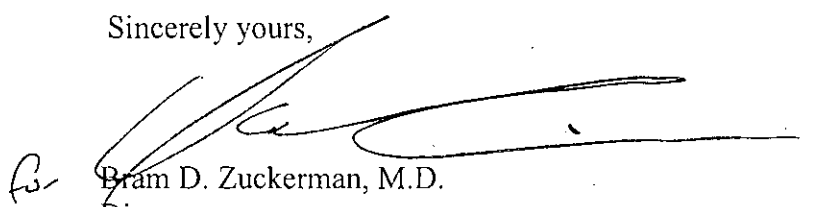
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110374

Device Name: Max Pulse

Indications For Use:

The device provides noninvasive measurement of pulse waveform and heart rate by photoelectric plethysmography. The anatomical site for taking the measurement is the left index finger. The device is intended for use with patients age 18 years and older and with a weight of 100 lbs or greater. The device is indicated for use in hospitals, health care clinics and physicians' offices

Prescription Use____X____ OR Over-The-Counter Use

(Per 21CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110374